

REMARKS

Claims 1, 2, 4, 5, 10, 12, and 17-19 are pending in this application after entry of the present amendment. Claims 6-9 have been canceled without prejudice as being drawn to a non-elected invention. Claim 3 has been canceled and claims 1, 2, 4, 5 and 10 have been amended as discussed below. New claims 17-19 have been added. Support for the new claims can be found throughout the specification, most particularly on pages 7-10, and in Example 3.

§ 112, First Paragraph Rejection- Written Description

Claim 1-3, 5, 10 and 12 were rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. Claim 3 has been canceled. Applicant respectfully submits that amended claim 1, and claims 2 and 4 dependent thereon, and amended claim 5, and claims 10 and 12 dependent thereon, satisfy the requirements of 35 U.S.C. § 112, first paragraph.

Claim 1 has been amended to recite an isolated p42 nucleic acid encoding a p42 polypeptide from the C-terminal processing fragment of *Plasmodium falciparum* major merozoite surface protein gp195, wherein said nucleic acid comprises a nucleic acid which hybridizes under high stringency conditions to the complement of the nucleic acid of SEQ ID NO: 1 or SEQ ID NO: 3. Thus, amended claim 1 recites the characteristic that the nucleic acid hybridizes under high stringency conditions to the complement of the nucleic acid of SEQ ID NO: 1 or SEQ ID NO: 3. Support for this amendment can be found on pages 7-10 and on page 23 of the specification. Claim 1 is additionally amended to further describe the p42 polypeptide encoded by the p42 nucleic acid. Support for this amendment can be found in the specification on page 7, last paragraph.

Similarly, amended claim 5 recites an *Agrobacterium*-mediated plant expression system for the production of a p42 polypeptide from the C-terminal processing fragment of *Plasmodium falciparum* major merozoite surface protein gp195, said system comprising a DNA construct consisting of operatively linked nucleic acid encoding a modified T-region but no vir-region, wherein said modified T-region comprises naturally occurring border sequences consisting of about 23 nucleotides at the extremities of said modified T-region, and wherein said modified T-

region further comprises a nucleic acid which hybridizes under high stringency conditions to the complement of the nucleic acid of SEQ ID NO: 1 or SEQ ID NO: 3. Support for this amendment can be found on pages 7-10 and on page 23 of the specification.

Claim 2 has been amended to specify that the nucleic acid of Claim 1 has enhanced RNA transcription and stability in a tobacco plant host cell. Support for this amendment can be found throughout the specification including page 7, first paragraph, and in the Examples. Claim 4 has been amended to depend from claim 1.

The Examiner cites *Fiers* and *Amgen* for the position that the written description requirement cannot be satisfied absent a reduction to practice of the invention (“[t]he protein itself is required”), and more generally asserts that the Applicant has failed to provide distinguishing attributes or characteristics of the claimed genus of nucleic acids. Applicant respectfully traverses since the specification both defines p42 nucleic acids (including NtMSP1.42 nucleic acids) and provides specific sequences of two possible p42 nucleic acids in SEQ ID NOs: 1 and 3. See for example, pages 7-10, 12, 22-24, and in the Examples and Figures. Moreover with respect to the genus as presently claimed, the specification also describes the conditions necessary to determine if a nucleic acid sequence hybridizes under high stringency conditions to the complement of the nucleic acid sequences set forth in SEQ ID NOs: 1 and 3. Specifically, on page 23, the specification states that one embodiment of the invention encompasses a nucleic acid that hybridizes under high stringency conditions to the nucleic acids disclosed therein. The specification then provides guidance as to what constitutes high stringency conditions.

One of skill in the art would understand that the Applicant had possession of the invention as recited in the amended claims. Applicant submits that amended claims 1, 2, 5, 10 and 12 satisfy the written description requirement and respectfully requests withdrawal of the rejection.

§ 112, First Paragraph Rejection- Enablement

Claim 3 and 12 were rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner asserts that a biological deposit is required to enable claim 3 and 12. Claim 3 has been canceled. Additionally, claim 3 was directed toward a nucleic acid construct, not a strain. The specification provides adequate support for the making of the constructs of the invention; see Example 3 of the specification.

Claim 12 is directed toward a method for production of a p42 polypeptide, comprising the steps of introducing an *Agrobacterium* strain into a plant cell wherein said *Agrobacterium* strain comprises at least one plasmid comprising the vir-region of a tumor-inducing plasmid, and at least one other plasmid comprising the modified T-region of Claim 5 but having no vir-region, wherein said plant cell becomes transformed; and extracting said p42 polypeptide from said transformed plant cell, wherein the *Agrobacterium* strain is *Agrobacterium tumefaciens* strain LBA4404. Thus, claim 12 is a method claim relating to the production of a p42 polypeptide from a transformed plant. The *Agrobacterium tumefaciens* strain LBA4404 is used as a tool to introduce the recited binary vectors into a plant cell. LBA4404 is a well-known strain commonly used to facilitate the transformation of plant cells. LBA4404 can be purchased through commercial suppliers and is, therefore, already available to the public. For example, LBA4404 can be purchased through Invitrogen as product number 18313-015. A copy of the online catalog page with information regarding this product is attached. Because LBA4404 is readily available to the public, there is no need to make a deposit of this strain in order to satisfy 35 U.S.C. § 112, first paragraph.

Additionally, the specification provides sufficient support to enable one of skill in the art to practice the method of claim 12. Example 3 sets forth the method of creating the binary vectors recited in claim 12. The vectors are based on well-known plasmids readily obtained where the T-region of one of the binary vectors is modified to contain a nucleic acid which hybridizes under high stringency conditions to the complement of the nucleic acid of SEQ ID NO: 1 or SEQ ID NO: 3. As discussed above, the specification also describes the conditions

necessary to determine if a nucleic acid sequence hybridizes under high stringency conditions to the complement of the nucleic acid sequences set forth in SEQ ID NOs: 1 and 3.

Furthermore, Example 3 sets forth a method of transforming a plant cell using an *Agrobacterium tumefaciens* strain, specifically the strain LBA4404. One of skill in the art would be able to practice the invention as set forth in claim 12 without undue experimentation. As such, no deposit is required to enable claim 12. Applicant requests withdrawal of this rejection.

§ 112, Second Paragraph Rejection

Claim 1

Claim 1 is rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, the Examiner has objected to the term “preferentially recognized”. Claim 1 has been amended and no longer recites the term “preferentially recognized”. As such, this rejection is rendered moot.

Claim 3

Claim 3 is rejected for improper antecedent basis. Claim 3 is canceled, thereby obviating the rejection.

Claim 10

Claim 10 is rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, the Examiner has objected to the term “virtually no T-region”. Claim 10 has been amended and no longer recites the term “virtually no T-region”. As such, this rejection is rendered moot.

§ 102(e) Rejections

Claims 1-3 and 5 were rejected under 35 U.S.C. § 102(e) as being anticipated by Guilley et al. Claim 3 has been canceled. The Applicant submits that Guilley does not anticipate amended claims 1, 2 and 5.

The Examiner asserts that Guilley discloses isolated nucleic acids encoding a p42 polypeptide and their transfection into a plant. However the P42 disclosed in Guilley is not the p42 of the present invention. The term p42 as it is defined in the present specification refers to the 42 KDa C-terminal processing fragment of the major merozoite surface protein of *Plasmodium falciparum*. See the specification at page 2, line 9-10, and page 7, last paragraph. The P42 disclosed in Guilley is a viral protein of the necrotic yellow vein furovirus (BNYVV). See Guilley column 3, lines 17-27. Furthermore, the definition provided in the specification is now incorporated into the independent claims.

Thus, the p42 polypeptide recited in the present claims and the P42 of Guilley are completely unrelated. As such, Guilley cannot anticipate the claims 1, 2 and 5. Accordingly, Applicant requests withdrawal of this rejection.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance and an early notification of such is solicited.

Please direct any calls in connection with this application to the undersigned at (415) 781-1989.

Respectfully submitted,

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